Guidance for Industry and FDA

Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions

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U.S. Department Of Health and Human Services
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Center for Devices and Radiological Health

Circulatory Support and Prosthetic Devices Branch
Division of Cardiovascular Respiratory and Neurology Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Catherine Wentz, Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Catherine Wentz at (301) 443-8243.

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Guidance[1] for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions

Introduction:
This guidance document describes a means by which cardiopulmonary bypass arterial line blood filter devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate cardiopulmonary bypass arterial line blood filter device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

This guidance document has been developed as a special control to support a change in classification from class III to class II. It identifies relevant material on preclinical studies and labeling to include in a 510(k) premarket notification application. We intend for it be used in conjunction with the FDA guidance documents listed below. These are also special controls. All FDA requirements regarding premarket notification submissions are not repeated in this document.

- Use of International Organization for Standardization (ISO) 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"

- 510k Sterility Review Guidance and Revision of 11/18/90

Scope:
This guidance is limited to the preclinical and labeling aspects of cardiopulmonary bypass arterial line blood filter devices. A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter non-biologic particles and emboli out of the blood. It is used in the arterial return line, (21 CFR 870.4260, DTM).

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

RISK TO HEALTH	CONTROLS
1. Damage to formed blood elements, e.g., clotting, hemolysis	Blood Studies: Evaluate hemolysis and cell depletion; blood component counts, blood component functionality, e.g., platelet function over a 6 hour circulation period. Test circuits over the range of labeled flow rates. Compare the subject device with predicate device using dynamic control circuits. Visual Inspection: Gross inspection for thrombus.
2. Excessive pressure drop resulting in inadequate blood flow, damage to device, structural integrity, damage to the line	Pressure and Leak Testing: Compare burst pressure for test and predicate devices using sustained pressure at 1.5 times the maximum anticipated pressure for intended use for 6 hours. Compare pressure drop to steady state at highest rated flow rate for test and predicate devices. Observe for leaks and structural integrity. Use blood or a blood analog as the testing medium.
3. Connections pull apart	Test and state the pull strength required to separate the connections; compare to predicate device.
4. No blood flow	Flow rate capacity: Determine the flow rate limitation(s) to assure safe and effective performance.
5. Does not provide efficient removal of solid and gaseous emboli	Filtration Efficiency: Determine filtration efficiency over the labeled range of particle size and flow rates. Compare performance of test device to predicate device. Micro Air Handling: Assess the ability of the device to remove free circulating microbubbles at several specified flow rates. Challenge the filter with gaseous microemboli introduced by adding a bubble oxygenator to the circuit. Record the microemboli activity at the inlet and out of the filter. FDA recommends testing a minimum of 5 filters of a type. Macro (Gross) Air Handling: Assess the gross air management of the device by the introduction of a bolus of air into the circuit. State the total volume of air introduced, flow rate of the air introduced, flow rate of the circuit, temperature and distance from the test device. FDA recommends testing a minimum of 5 filters of a type.

RISK TO HEALTH	CONTROLS
6. User error	Labeling: Include clear, concise instructions for use. Describe human factors considerations, e.g., troubleshooting guide, easy formatting of instructions for use, etc. Provide rated filtration efficiency, flow rate and duration of use (e.g., 6 hours), and other pertinent information obtained through performance testing. THE USE OF A BUBBLE DETECTOR MUST BE INCLUDED AS A CIRCUIT COMPONENT.
7. Not compatible with blood	Biocompatibility testing: Perform testing recommended in the FDA guidance on ISO 10993: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, dated May 1, 1995 to assure that the materials used are non-toxic for the intended use. Include sensitization, pyrogenicity, acute systemic toxicity, mutagenicity, cytotoxity, irritiation, and hemocompatibility/hemolysis testing.
8. Infection/pyrogenicity complications	Sterilization: Perform sterilization validation to ensure that the sterilization process is capable of providing a Sterility Assurance Limit (SAL) of 10^{-6}. Perform biological, pyrogen, and bioburden testing to ensure acceptable limits of biological contaminants. Shelf-life: Validate the package shelf-life to ensure that the device will remain sterile for the period of time specified on the label: Test simulated or real shipment and handling conditions: dropping, vibration, stacking, temperature, humidity, and atmospheric pressure extremes followed by device functionality testing. Study real or accelerated aging: if accelerated aging is used, plan to conduct a real time follow-up to verify the accelerated results. Include package integrity and barrier property assessment: using validated physical or microbial-based methods.